

Citation:

Carels RA, Young KM, Coit C, Clayton AM, Spencer A, Hobbs M. Can following the caloric restriction recommendations from the Dietary Guidelines for Americans help individuals lose weight? *Eat Behav.* 2008 Aug; 9 (3): 328-335. Epub 2008 Jan 4.

PubMed ID: [18549992](#)

Study Design:

Randomized controlled trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To investigate the relationship between creating a consistent, self-reported energy deficit of at least 500kcal per day and weight loss
- The relationship between self-monitoring adherence and daily energy intake and expenditure and weight loss was also examined.

Inclusion Criteria:

- Overweight or obese (BMI $\geq 27\text{kg/m}^2$)
- Non-smokers
- Received a physician's clearance.

Exclusion Criteria:

- Cardiovascular disease
- Musculoskeletal problems preventing moderate physical activity
- Insulin-dependent diabetes.

Description of Study Protocol:**Recruitment**

Subjects were recruited through advertisements in local and regional newspapers to take part in a weight loss intervention at a Midwestern University.

Design

Randomized controlled trial, 14-week multi-phase weight-loss intervention.

Dietary Intake/Dietary Assessment Methodology

Participants recorded all food intake over the 14-week intervention in daily food diaries.

Blinding Used

Not applicable.

Intervention

- All participants received a LEARN weight loss program manual. The LEARN program emphasizes gradual weight loss, progressively increasing physical activity and decreasing energy and fat intake through permanent lifestyle changes
- Subjects were also given an accelerometer to track energy expenditure and written and verbal instructions to create at least a 500kcal per day deficit. All subjects were given a 5% total body weight loss goal during the 14-week intervention.

Subjects were randomly assigned to one of the following groups:

- Self-help (SH) who received only the intervention described above
- Therapist-assisted self-help (TASH) who received two 45-minute face-to-face sessions and weekly 15-20 minute telephone calls with a counselor.

Statistical Analysis

- Chi-square analyses and analysis of variance were used to examine the differences in demographic information and dietary intake variables between those who completed and those who did not complete the intervention
- ANOVA was used to compare overall weight loss in participants whose average energy deficit through the intervention was greater than or equal to 500 kcal per day (N=35) to those who reported a deficit less than 500kcal per day (N=9)
- Multiple linear regression, controlling for intervention group and baseline BMI, was used to examine the relationship between the amount of total energy deficit or excess and overall weight loss. Hierarchical regression was used to examine the relationships between daily energy deficit and weekly weight-loss
- Repeated measures ANOVA was used to examine self-monitoring adherence by examining

average weekly self-monitoring frequency over three time periods, 1) beginning (first four weeks), 2) middle (middle five weeks), and 3) final (final five weeks). Multiple linear regression was employed to investigate the relationship between total days of self-monitoring and overall weight-loss. Intervention group and baseline BMI were controlled in these analyses. Hierarchical regression was also used to examine the relationship between weekly self-monitoring and weekly weight-loss.

- Multiple regression, controlling for intervention group and baseline BMI, was used to examine the relationship between average energy expenditure and intake throughout the intervention and overall weight loss. Hierarchical regression was used to examine the relationship between daily energy intake and expenditure, exercise and weekly weight loss.

Data Collection Summary:

Timing of Measurements

Energy intake and energy expenditure was measured daily across the 14-week intervention, weight was measured by participants weekly and weight was measured by study personnel at baseline and 14-weeks.

Dependent Variables

Body weight was measured at baseline and 14-weeks by study personnel. Height was measured at baseline. These measurements were used to calculate BMI and total weight loss during the weight loss program.

Independent Variables

- Energy expenditure was measured daily using an accelerometer
- Self-monitoring was done daily and measured by the average days per week that the participant self-monitored, as well as the total number of days over the program that the subject self-monitored
- Energy intake was measured daily using a food diary.

Control Variables

Intervention group, baseline BMI.

Description of Actual Data Sample:

- *Initial N:* 54
 - N=28 for SH
 - N=26 for TASH

- *Attrition (final N):* 44
 - N=21 for SH
 - N=23 for TASH
- *Age:* 46.2±8.9 years
- *Ethnicity:* 94% Caucasian
- *Other relevant demographics:*
 - 78% female
 - 85% had an annual income greater than \$30,000 per year
 - 66% had a baccalaureate degree
- *Anthropometrics:*
 - Mean BMI: 36kg/m²
 - Mean weight: 99kg
- *Location:* United States.

Summary of Results:

- Mean weight loss over the 14-week intervention was 4.8±5.2kg (Range: -17.0 to +3.7kg). Weight loss in the SH and TASH groups did not differ significantly
- Individuals who averaged an energy deficit of greater than 500kcal per day lost nearly four times as much weight (5.7±5.0kg) as did individuals whose average energy deficit was less than 500kcal per day (1.6±3.4kg) (P=0.03)
- Greater average reported energy deficit was significantly related to greater overall weight loss (P<0.01)
- Greater self-monitoring throughout the program was significantly associated with greater overall weight loss (P<0.0001) Self-monitoring throughout the program accounted for 25% of the variance in overall weight loss Individuals who lost 5% of their body weight during the intervention self-monitored more than twice as many days as did individuals who did not lose 5% of their body weight (P<0.001)
- Participants with greater average energy expenditure and lower energy intake throughout the intervention lost significantly more weight.

Overall Weight Loss (Outcome Variable)	β	T	P-value
Total energy intake	-0.36	-2.63	0.01
Energy expenditure	-0.03	0.19	0.85
Exercise	0.05	0.33	0.75
Daily calorie deficit	-0.42	-2.68	0.01
Daily self-monitoring	0.42	3.32	0.00

Author Conclusion:

The authors concluded that self-monitoring of energy intake and expenditure were significantly,

positively associated with weight loss.

Reviewer Comments:

- *The relatively small sample size resulted in modest statistical power*
- *Adjustments for possible confounding factors were not made.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study groups comparable?	Yes

3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A

6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes

8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes